

Policy terminated because no longer standard of care.

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1.0 Definition of the Procedure

Biventricular pacing is a technique used to coordinate the contraction of the ventricles, thus improving the hemodynamic status of the patient with congestive heart failure (CHF). Cardiac resynchronization therapy (CRT) with biventricular pacing improves both hemodynamic and clinical performance of patients with CHF. Biventricular pacemakers use three leads, one in the right atrium, and one in each ventricle.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid-eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is

medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the Basic Medicaid Billing Guide, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/medbillguide.htm>

EPSDT provider page: <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>

3.0 When the Procedure Is Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

Each recipient’s condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers biventricular pacemakers as a treatment for congestive heart failure who meet the following criteria:

- a. NYHA Class III or IV
- b. Left ventricular ejection fraction less than 35%
- c. QRS duration of greater than or equal to 150msec.
- d. Treatment with one or more of the following pharmacological/medical regimes prior to implant:
 1. Beta-blocker or angiotensin receptor blocker
 2. Ace inhibitor or angiotensin receptor blocker
 3. Digoxin
 4. Diuretics

4.0 When the Procedure Is Not Covered

IMPORTANT NOTE: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this

section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

Biventricular pacemakers as a treatment for congestive heart failure is not covered when the medical necessity criteria listed in Section 3.0 are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover biventricular pacemakers for patients whose heart failures or ventricular arrhythmias are reversible or temporary.

4.1 History of or Active Substance Abuse

Must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

4.2 Psychosocial History

Psychosocial history that would limit ability to comply with medical care pre and post transplant.

4.3 Medical Compliance

Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All biventricular pacemakers must be prior approved by DMA.

6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices must be utilized for implantation.

Implants, products, and devices must be used in accordance with the applicable FDA requirements current at the time of the procedure.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1994

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
4/30/12	Throughout	Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Physicians bill professional services on the CMS-1500 claim form.

Hospitals bill for services on the UB-92 or UB-04 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Covered biventricular pacemaker codes include

33213	33224	33225	33226
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D. Reimbursement

Providers must bill their usual and customary charges.